The second terms of the second second

## **CLAIMS**

- 1. A method for cancer diagnosis or prognosis which comprises:
- (a) treating a sample from a human or animal subject with a solid phase under conditions to bind telomerase to the solid phase;
- (b) separating the solid phase from the treated sample to form a test sample which is optionally treated to elute bound telomerase from the solid phase; and
- (c) assaying the test sample for telomerase activity, wherein detection of telomerase activity in the sample is indicative of cancer in the subject.
- 2. A method according to claim 1, wherein the solid phase is assayed for telomerase activity in step (c).
- 3. A method according to claim 1 or claim 2, wherein the sample comprises target whole cells, which are treated in step (a) to form a lysate to release telomerase for binding to the solid phase.
- 4. A method according to claim 3, wherein the sample comprising the target whole cells comprises a mixture of cell populations which is subjected to a sorting step before step (a) to isolate the target whole cells in the sample.
- 5. A method according to claim 4, wherein the sorting step comprises flow cytometry sorting or a step of binding the target whole cells to a solid phase affinant for the target whole cells.
- 6. A method according to claim 5, wherein the affinant is present on the solid phase for binding the telomerase.
- 7. A method according to claim 5 or claim 6, wherein the affinant comprises an antibody specific to the target cells.

- 8. A method according to any one of claims 5 to 7, wherein the affinant is specific for epithelial cells.
- 9. A method according to any one of claims 4 to 8, wherein the mixture of cell populations is from blood, bone marrow, a pleural effusion, urine, saliva, sputum, faeces, spinal fluid, a cervical smear, a buccal swab, or a needle biopsy sample.
- 10. A method according to claim 9, wherein detection of telomerase activity in the sample is further indicative of micrometastasis in the subject.
- 11. A method according to any one of the preceding claims, wherein the solid phase comprises a particulate material.
- 12. A method according to claim 11, wherein the particulate material comprises polymeric beads.
- 13. A method according to claim 12, wherein the polymeric beads have a diameter in the range of from  $1\mu$  to  $6\mu$ m.
- 14. A method according to any one of claims 11 to 13, wherein the particulate material is magnetic.
- 15. A method according to any one of the preceding claims, wherein the step (c) of assaying for telomerase activity uses a telomeric repeat assay protocol.
- 16. Use of a solid phase for detecting telomerase activity in a sample by treating the sample with the solid phase so as to bind the telomerase thereto and assaying the solid phase for telomerase activity.

20-04-2001



- 17. Use of a solid phase according to claim 18, in a method according to any one of claims 1 to 15.
- 18. Use of a kit for detecting telomerase activity, wherein the kit comprises a solid phase for binding telomerase, and one or more components for assaying for telomerase activity, and wherein the solid phase is used to bind telomerase.
- 19. Use according to claim 18, wherein the solid phase comprises a particulate material.
- 20. Use according to claim 19, wherein the particulate material comprises polymeric beads.
- 21. Use according to claim 20, wherein the polymeric beads have a diameter in the range of from 1 µm to 6 µm.
- 22. Use according to any one of claims 19 to 21, wherein the particulate material is magnetic.
- 23. A kit for detecting telomerase activity, comprising a solid phase for binding telomerase and one or more components for assaying for telomerase activity, wherein the solid phase comprises an affinant for binding target whole cells.
- A kit for detecting telomerase activity, comprising a solid phase for binding telomerase and one or more components for assaying for telomerase activity, which further comprises a second solid phase for binding target whole cells.
- 25. A kit according to claim 24, wherein the second solid phase comprises an affinant for binding target whole cells.
- 26. A kit according to claim 23 or claim 25, wherein the affinant comprises an antibody specific to the target cells.



- A kit according to any one of claims 23, 25 or 26, wherein the affinant is specific for 27. epithelial cells.
- 28. A kit according to any one of claims 23 to 27, wherein the one or more components for assaying telomerase activity comprise a substrate for telomerase elongation.
- 29. A kit according to claim 28, wherein the substrate for telomerase elongation is present on the solid phase for binding telomerase.
- A kit according to any one of claims 23 to 29, wherein the one or more components for 30. assaying telomerase activity comprise components for a telomeric repeat assay protocol.
- 31. A kit according to any one of claims 23 to 30, wherein the one or more components for assaying telomerase activity include oligonucleotide primers to amplify the telomerase product.
- 32. Use of a kit according to any one of claims 23 to 31, for the detection of cancer cells.
- Use according to claim 32, wherein the kit further comprises means for assaying an 33. mRNA diagnostic for cancer.